

WHAT IS CLAIMED IS:

- 1 1. A liposomal topotecan unit dosage form, said unit dosage form
2 comprising:
3 a lipid; and
4 a topotecan dosage of from about 0.01 mg/M²/dose to about
5 7.5 mg/M²/dose, wherein said liposomal topotecan unit dosage form has a drug:lipid ratio
6 (by weight) of about 0.05 to about 0.2.
- 1 2. The liposomal topotecan unit dosage form of claim 1, wherein said
2 drug:lipid ratio (by weight) is about 0.05 to about 0.15.
- 1 3. The liposomal topotecan unit dosage form of claim 1, wherein said
2 lipid comprises a mixture of sphingomyelin and cholesterol.
- 1 4. The liposomal topotecan unit dosage form of claim 1, wherein said
2 lipid comprises sphingomyelin and cholesterol in a ratio by weight of about 30:70 to
3 about 60:40.
- 1 5. The liposomal topotecan unit dosage form of claim 1, comprising
2 from about 1 mg/M²/dose to about 4 mg/M²/dose of topotecan.
- 1 6. A liposomal topotecan formulation, wherein said liposomal
2 topotecan formulation retains greater than 50% active lactone species after 12 hours in
3 blood circulation.
- 1 7. The liposomal topotecan formulation of claim 6, wherein said
2 liposomal topotecan formulation retains greater than 80% active lactone species after 12
3 hours in blood circulation.
- 1 8. A liposomal topotecan formulation comprising topotecan,
2 sphingomyelin, cholesterol and a divalent cation ionophore.
- 1 9. The liposomal topotecan formulation of claim 8, wherein said
2 divalent ionophore is present in trace amounts.
- 1 10. The liposomal topotecan formulation of claim 8, comprising a
2 drug:lipid ratio (by weight) of about 0.05 to about 0.2.

- 1 11. The liposomal topotecan formulation of claim 10, wherein said
2 drug:lipid ratio (by weight) is about 0.05 to about 0.15
- 1 12. The liposomal topotecan formulation of claim 11, comprising trace
2 amounts or greater of a divalent ionophore.
- 1 13. A method of treating a solid tumor in a human afflicted therewith,
2 said method comprising administering to said human an effective amount of a topotecan
3 dosage of claim 1 in a pharmaceutically acceptable carrier.
- 1 14. The method of claim 13, wherein said solid tumor is selected from
2 the group consisting of solid tumors of the lung, mammary, colon and prostate.
- 1 15. The method of claim 13, further comprising co-administration of a
2 treatment for neutropenia or platelet deficiency.
- 1 16. A method of treating solid tumors in a mammal, said method
2 comprising:
3 administering to said mammal having a solid tumor of the lung, mammary
4 and/or colon a liposomal topotecan formulation having a drug:lipid ratio (by weight) of
5 about 0.05 to about 0.2.
- 1 17. A method of treating solid tumors in a mammal, said method
2 comprising:
3 administering to said mammal having a solid tumor of the lung, mammary
4 and/or colon a liposomal topotecan formulation comprising from about 0.01 mg/M²/dose
5 to about 7.5 mg/M²/dose of topotecan for an interval regime, wherein said interval regime
6 is once a day for at least two consecutive days.
- 1 18. The method of treating solid tumors of claim 17, wherein said
2 interval regime is at least once a week.
- 1 19. The method of treating solid tumors of claim 17, wherein said
2 interval regime is at least once every two weeks.
- 1 20. The method of treating solid tumors of claim 17, wherein said
2 interval regime is at least once every three weeks.

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1 21. The method of treating solid tumors of claim 17, wherein said
2 liposomal topotecan formulation has a drug:lipid ratio (by weight) of about 0.05 to about
3 0.2.

1 22. A method of treating solid tumors in a mammal comprising
2 administering to an animal having a solid tumor of the lung, mammary
3 and/or colon a liposomal topotecan formulation comprising from about 0.01 to about
4 7.5 mg/M²/dose of topotecan every three days.

1 23. A liposomal camptothecin unit dosage form, said unit dosage form
2 comprising a lipid, a camptothecin dosage of from about 0.015 mg/M²/dose to about
3 1 mg/M²/dose and having a drug:lipid ratio (by weight) of about 0.05 to about 0.2.

1 24. The use of topotecan in the manufacture of a medicament
2 comprising a liposome having a sphingomyelin to cholesterol ratio (by weight) of from
3 about 30:70 to about 60:40 for use in treating solid tumors in a mammal.

1 25. The use of claim 24, for treating solid tumors of the lung,
2 mammary and colon.